**SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY**

**GUIDELINE FOR SYNOPSIS FOR MS/MD/MDS & M. Phil/ PhD**

Synopsis is the brief summary, an outline of the research project intended to be conducted by the MS, MD, MDS and M. Phil or PhD scholars. It should consist on 6-8 pages having 1200-1500 words. The following structure should be followed:

## Table of Contents

## Title Page

- Title of the research project should be brief and should reflect the main concept and the study design. The title should be concise, specific and informative. As for example:
    - Effectiveness of short term intake of cinnamon in type 2 diabetes patients: Randomized controlled trial
- The scholar's name, highest qualification and job title should be indicated.
- Supervisor's name, highest qualification and organization/ department affiliation should be mentioned

## Abstract/ brief summary

Structured abstract of 250 words in length should be provided with:

- **Background** (Including primary objective)
- **Methods**
- **Discussion**
- **3-5 keywords:**

  **Include important relevant and significant 'keywords' to allow the identification of the key elements of the study.**
- The Key words according to MeSH terms should also be provided. Refer to the MeSH browser: https://www.nlm.nih.gov/mesh/MBrowser.html

## Introduction: (500-600 words)

The importance of introduction is to give a brief overview about the subject matter on which research is being conducted and provide the appropriate scientific background. It should be built in such a way as to lead to the rationale (why the research is being conducted) of the research project. Following headings should be included

- **Brief overview**: Sub-heading under it may be provided to make the points clear.
- **Rationale (What research question are you trying to answer and why)**

## Research question

The research question for the research project should include **PICO**:

- **Population** : relevant participants/ patients for the research project
- **Intervention or indicator**: the medicine/ surgery/ educational intervention should be clarified.
- **Comparison:** Is there a comparator or alternative approach/ strategy for the treatment?
- **Outcome:** What are the patient relevant consequences/ effect?
- The FINER (Feasible, Interesting, Novel, Ethical and Relevant) criteria should be utilized in the development of a good research question.

<u>Example of research question:</u>

- What is the effect of honey addition to cough syrup for the relief of cough in throat infections in children?
    - Population: children

- Intervention: honey
- Comparator (standard treatment): cough syrup
- Outcome: relief of cough

## Objectives

These should be **SMART:**

- **S:** specific
- **M:** measurable
- **A:** achievable
- **R:** relevant
- **T:** time bound

Example of objectives:

- To assess the effect of honey addition with cough syrup in relief of cough in children with throat infection after one week of its use.

## Operational Definitions:

Is the definition of the exposure and outcome variables of interest in context to objective in a particular study and their means of measurement/determination.

Examples:

- Anemia
- Effectiveness
- PPH
- Wound healing

## Hypothesis

A hypothesis is a specific statement of prediction. It describes in concrete (rather than theoretical) terms what you expect will happen in your research project.

Example of hypothesis:

- Honey and cough syrup have equal effectiveness in the relief of cough in children with throat infections after one week of its use.

## Methodology: (250-300 words)

Include the following in the methodology section:

**Study design:** Be specific. Your study type should be interventional that is one group should be given intervention along with standard treatment and other or control group should be on standard or placebo treatment. The intervention can be any drug, procedure or method.

The study design should be

- Randomized controlled Trial
- Non- Randomized Controlled Trial
- Cross sectional Comparative

Generally, in a Randomized Controlled Trial, study participants are randomly assigned to one of two groups: the experimental group receiving the intervention that is being tested and a comparison group (controls) which receives a conventional treatment or placebo.

**Study setting**: Where is the study being conducted?

**Study duration**: For how long the study is being conducted for?

**Study population**: Who are the study participants? Provide the inclusion and exclusion criteria.

**Sample Size:** How the sample size was calculated? WHO sample size software can be used for its calculation. Also indicate which formula for sample size calculation was used and values put in it to calculate the given sample size.

**Sampling Technique**: How the sampling was done? Whether the sample was randomly chosen or non-probability convenient sampling done?

- Randomization: In case of randomized controlled trial, how was randomization into groups done?
- Blinding: In case of randomized controlled trial, tell whether the patients were blinded to the intervention/ control.

**Data collection Procedure**: Highlight the following:

- Permission form hospital ethical committee and informed written consent from all participants.
- How the data will be collected?
- Will a validated data collection tool (questionnaire) be used?
- Is the questionnaire pre-tested? Who will collect the data?
- All Lab investigations to be done for research purposes
- Any screening procedures to be performed
- Description of the Case Report Form (CRF) and Proforma to be filled out
- How the variables in the study will be measured,

- What is the exposure variable? (Define in Operational definitions as well)
- What is the outcome variable, how will these be diagnosed or measure and their time of measurement (Define in Operational definitions as well)
- Describe if Placebo is to be given
- Address how to keep track of drop outs & lost to follow-up
- How to monitor compliance with study medication & placebo
- Standard care and treatment will be given to all in study irrespective of being in intervention or placebo arm

  During data collection writing also discuss that
- Who will collect it?
- Who will ensure confidentiality of the participants?
- How will be data checked for completeness?
- What will be procedures for data entry?

**Plan of analysis**: (150-250)

Give an outline of the plan of analysis along with the statistical software in which it will be performed. Include the following:

- What will be measured and how? For example, mean and standard deviation will be calculated for continuous variables and proportions will be calculated for categorical variables.
- Give an outline of the statistical tests that will be conducted example student t-test, chi-square test, odds ratio etc.

**Ethical consideration**: Address the issues of ethical consideration like:

- How will the confidentiality and privacy of participants will be ensured?
- Is the treatment being given in randomized controlled trial justifiable? What are its harm and benefits to the patient?
- Give an informed consent form in both English and Urdu Language that will be used to take written informed consent form the participants.
- All additional tests to be done for research purpose are ethical with no undue harm or risk for the subjects
- Will there be any cost to subject for any medication, test or investigation done while in study
- Need to specify modified consent process for protected populations like pediatric, orphans and pregnant populations
- In pediatric populations children (subjects) give assent and parents/guardians give consent
- Informed consent should be a proper detailed, informative and explanatory informed consent process and not just signing of the informed consent form

## Acknowledgements

State source of funding for research, if any and mention any conflict of interest. Acknowledge any person who contributed to the study protocol development

## References

References should follow Vancouver style. Follow the Vancouver style from the following document:

http://library.vcc.ca/downloads/VCC_VancouverStyleGuide.pdf

## Annexure

Annexure should be placed after the references in the synopsis document. In the annexure of the synopsis, provide the following:

- Annexure A: proforma or the Data collection tool- the questionnaire
- Annexure B: Informed consent form in English and in Urdu designed to be signed by the study participant.

## Formatting Requirements:

- The synopsis should be typed in double spacing on A-4 paper (8.25" x 11.70" = 21.0 cms x 29.70 cms) white bond paper with one inch (2.5 cms) margin on both sides.
- The font size should be 12", in Times New Roman or Arial
- The main headings should be bold and capital letters in 12" size
- The sub-heading should be bold and 12" size

**Plagiarism Policy**: University follows the standard plagiarism policy of Higher Education Commission (HEC) for Synopsis and Thesis. No synopsis will be proceeded, which will not fulfill the uniform requirement of similarity index of < 19%.